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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/697,079	10/27/2000	Donna K. Fox	0942.4460002/RWE/BJD	7547

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EXAMINER

JOHANNSEN, DIANA B

ART UNIT

PAPER NUMBER

1655

DATE MAILED: 01/15/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/697,079

Applicant(s)

FOX ET AL

Examiner

Diana B. Johannsen

Art Unit

1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 December 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 45-49 and 52 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 45-49 and 52 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 19, 2001 has been entered.

2. Claim 45 has been amended and claims 45-49 and 52 are now pending. Any rejections not reiterated in this action have been withdrawn as being obviated by the amendment of the claims. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 102

3. Claims 45-47, 49 and 52 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Chenchik et al (U.S. Patent No. 5,565,340 [10/15/1996; filed 1/27/1995]).

Chenchik et al teach restriction digestion of PCR products prepared using a DNA polymerase that was inactivated with anti-DNA polymerase, and thereby teach compositions comprising restriction endonucleases and polymerase inhibitors (col 20, lines 38-67; col 21, lines 1-32). With respect to claims 46-47, the composition taught by Chenchik et al comprises TthSTART (anti-Tth polymerase) (col 21, lines 6-9). With respect to claim 49, it is an inherent property of the compositions taught by Chenchik et

al that they are "stable upon storage" (e.g., such compositions would be stable when frozen). Further, it is noted that Chenchik et al teach providing restriction endonucleases and polymerase inhibitors in kits, and thereby exemplify reagents that are "stable upon storage", as required by the instant claim (col 11, lines 10-24). With respect to claim 52, the compositions taught by Chenchik et al further comprise buffers (col 21, lines 28-32). Chenchik et al thereby clearly anticipate the compositions of the instant claims.

With respect to the rejection of claims 45-49 and 52 in the Office action of paper no. 6, the response traverses the rejection on the grounds that "the composition that remained after separation of the PCR products could not have contained one or more restriction endonucleases". However, applicants' arguments are not pertinent to the instant rejection. The claims rejection in the Office action of paper no. 6 recited the limitation "wherein said composition does not comprise a nucleic acid molecule". However, the instant claims do not recite this limitation. Accordingly, as discussed above, the composition anticipating the instant claims is that discussed at col 21, lines 28-32 of Chenchik et al (i.e., the composition containing PCR products and reagents, restriction enzyme and enzyme buffer), rather than the composition discussed in the Office action of paper no. 6. Accordingly, applicants' arguments are not persuasive.

4. Claims 45-49 and 52 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Okura et al (U.S. Patent No. 6,060,283 [5/2000; filed 6/1997]).

Okura et al disclose a composition comprising TAQSTART antibody and the restriction enzymes *HindIII* and *SphI*, and a composition comprising TAQSTART

antibody and the restriction enzymes *NofI* and *SphI* (col 10, lines 11-51, particularly lines 33-35 and 48-50). With respect to claim 49, it noted that it is an inherent property of the reagents taught by Okura et al and of the compositions taught by Okura et al that they are "stable upon storage" (e.g., such compositions would be stable when frozen). With respect to claim 52, it is noted that the compositions disclosed by Okura et al comprise buffers (e.g., diluted PCR buffer). Accordingly, Okura et al clearly anticipate the compositions of the instant claims.

Claim Rejections - 35 USC § 103

5. Claim 48 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chenchik et al (U.S. Patent No. 5,565,340 [10/15/1996; filed 1/27/1995]).

Chenchik et al teach restriction digestion of PCR products prepared using a DNA polymerase that was inactivated with anti-DNA polymerase, and thereby teach compositions comprising restriction endonucleases and polymerase inhibitors (col 20, lines 38-67; col 21, lines 1-32). The composition taught by Chenchik et al comprises TthSTART (anti-*Tth* polymerase) (col 21, lines 6-9). Chenchik et al do not teach a composition including any of the particular anti-polymerase antibodies of claim 48. However, Chenchik et al disclose the use of TAQSTART (anti-*Taq* polymerase) in PCR (col 19, line 45-col 20, line 34). Further, Chenchik et al teach that a variety of polymerases may be employed in their PCR methods, including *Taq* and *Pfu* polymerases (col 11, lines 25-35), and that their methods may employ antibodies that bind to and inactivate these polymerases (col 11, lines 43-50). Accordingly, in view of

Chenchik et al's teachings with respect to the use of a variety of polymerases and antibodies in their methods, and absent a showing by applicant of unexpected results with, e.g., a particular combination of reagents, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have modified the compositions of Chenchik et al so as to have prepared a composition comprising anti-*Taq* or anti-*Pfu*, as required by claim 48, during the course of practicing the methods taught by Chenchik et al. As Chenchik et al teach that a variety of polymerases and anti-polymerase antibodies may be employed successfully in their methods, an ordinary artisan would have been motivated to have made such a modification and employed either anti-*Taq* and/or anti-*Pfu* in any instance when those reagents were most readily available to and usable by the practitioner, for the advantages of convenience, efficiency, and cost-effectiveness.

Conclusion

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diana B. Johannsen whose telephone number is 703/305-0761. The examiner can normally be reached on Monday-Friday, 7:00 am-3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on 703/308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are 703/305-3014 for regular communications and 703/305-4242 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703/308-0196.

Diana B. Johannsen
January 11, 2002


W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600